

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PCT

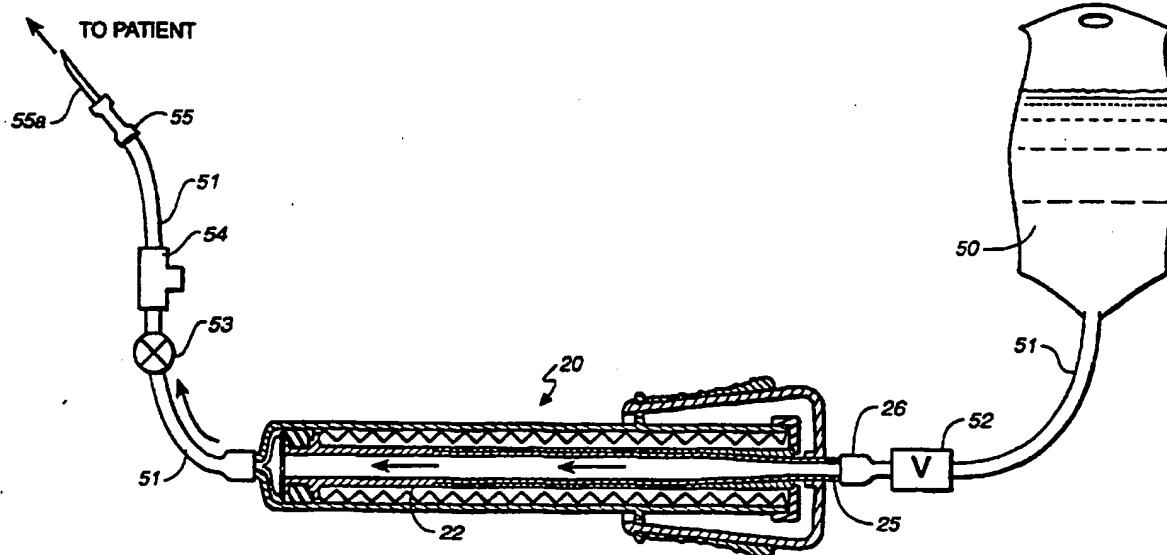
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 1/00, 5/178, 5/00, 5/315	A1	(11) International Publication Number: WO 94/14482 (43) International Publication Date: 7 July 1994 (07.07.94)
(21) International Application Number: PCT/US93/10205		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 22 October 1993 (22.10.93)		
(30) Priority Data: 07/991,610 23 December 1992 (23.12.92) US		Published <i>With international search report.</i>
(71) Applicant: ABBOTT LABORATORIES [US/US]; 1212 Terra Bella Avenue, Mountain View, CA 94043 (US).		
(72) Inventors: AMBRISCO, William, M.; 708 Simon Street, Hayward, CA 94541 (US). IWAMASA, Laurette; 6279 Lido Court, Newark, CA 94560 (US). PANTAGES, Anthony, J.; 133-B Kittoe Drive, Mountain View, CA 94043 (US).		
(74) Agents: THIBAULT, Harry, G.; Abbott Laboratories, 1212 Terra Bella Avenue, Mountain View, CA 94043 (US) et al.		

(54) Title: IMPROVED IN-LINE SAMPLING SYSTEM INCORPORATING AN IMPROVED BLOOD SAMPLING DEVICE



(57) Abstract

A blood sampling system which incorporates a fluid storage mechanism (20) which can be disposed along the longitudinal axis of a fluid line (51) extending from an injection site (55) to a fluid supply (50). Both the main body portion (21) of the fluid storage mechanism (20) and a fluid draw element (22) of the fluid storage mechanism (20) are axially aligned with the longitudinal axis of the fluid line (51). The fluid storage mechanism (20) also incorporates a vortex inducer element (28) at the distal end (24) of the fluid draw element (22) to induce a swirl of fluid to cleanse the fluid storage mechanism (20) once a sample drawn into the fluid storage mechanism (20) has been returned to the patient. An alternative embodiment of the fluid storage mechanism (20) includes a volume control device (240).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

-1-

**IMPROVED IN-LINE SAMPLING SYSTEM INCORPORATING AN IMPROVED BLOOD
SAMPLING DEVICE**

BACKGROUND OF THE INVENTION

Field of the Invention

- 5 The present invention relates to blood sampling systems and, in particular, to an improved blood sampling device usable in such systems, and enabling in-line sampling.

State-of-the-Art

- 10 Arterial and venous infusion lines are used to introduce fluids into the blood stream of a patient. Devices of various types have long been used to regulate the flow of fluid from a fluid supply to an injection site. Typically the injection site is also used to take periodic blood samples from the patient.

- 15 In such an instance, the flow of fluid from the fluid supply can be turned off to allow blood to flow in the reverse direction through the arterial line to facilitate taking such blood samples. Patient requirements and the treatment protocol prescribed will dictate the frequency of the blood sampling procedure. When the frequency of sampling becomes greater, according to the needs of the patient and the 20 treatment protocol, it becomes desirable to improve the efficiency of the blood draw procedure and eliminate waste whenever possible.

- A particular situation of note relates to neonatal patients in which the blood supply is considerably smaller than the blood supply of adults and the need to maximize efficiency in the blood sampling procedure and to avoid unnecessary discharge of blood is of particular concern.

-2-

A known sampling procedure for drawing blood from an arterial line utilizes a plurality of stopcock mechanisms that prevent the flow of fluid from the fluid source and allow blood to flow from the patient into a collecting syringe connected to a removal port formed in one of the stopcocks. However, such a procedure necessarily will draw a mixture of fluid and blood in the first iteration of the sampling procedure, and the initial sample is discarded. A second sample is then taken, such second sample considered to be a representative sample of blood. Because the discarded sample includes not only fluid from the fluid source, but some of the patient's blood, such a two-sample process causes an unnecessary loss of blood to the patient. Other undesirable effects associated with the above noted sampling process includes the increased potential for introduction of air into the arterial line and the increased potential for introduction of contaminants into the patient's bloodstream.

An effort to modify the above noted two-step sampling process is noted in U.S. Pat. No. 4,673,386 entitled "Blood Sampler Device" and issued to Gordon. Gordon describes a mechanism for eliminating the need to undertake a two-step process to withdraw blood through an arterial line. The Gordon device comprises a combination pump/storage mechanism which accommodates the return flow of the downstream fluid such that a single sample can be taken from a removal port, that sample being clear of supply fluid and therefore representative of the patient's blood supply. The Gordon patent describes a method and apparatus for drawing blood from an injection site through an arterial line connected to a fluid supply.

The apparatus includes a variable capacity pump mechanism also having an interior chamber, first and second ports connected to the variable capacity interior chamber, and a retractable piston disposed within the housing to traverse within the chamber. A piston sealing member is provided about the chamber in slidably sealing relationship with the chamber to cause fluid to be drawn into the chamber, thereby facilitating extraction of the blood sample along the arterial line without the need to discharge an initial sample containing disproportionate amounts of supply fluid.

However, the Gordon device incorporates features which may be undesirable to a caregiver conducting the sampling process. For example, although the Gordon device is in fluid communication with the arterial lines transmitting fluid to the patient, the variable capacity chamber is disposed transverse to such line to cause an imbalance in

-3-

such arterial line both prior to and during the sampling process. Moreover, the above-noted imbalance in the dual variable capacity storage device of Gordon is exacerbated during the sampling process making it difficult for a single attendant to conduct the sampling process. Although Gordon introduces certain desirable features to the sampling process, its awkward structure, and its bulkiness may be undesirable to the sampling process.

SUMMARY OF THE INVENTION

Accordingly, it would be desirable to provide a sampling device which 10 introduces a certain symmetry to the sampling system to enable the sampling system to be readily used by a single attendant. Such a device would be readily integrated into the sampling system to be concentric with the arterial line extending from the patient to the fluid source. Moreover, such device should incorporate a sheath 15 overlying the major elements of the sampling system to protect the system from outside contamination.

Further, the improved sampling device should incorporate a locking mechanism to limit the capacity of the sampling device. Further, the device should incorporate a swirl or vortex element to facilitate 20 removal of blood and fluid from the sampling device when the blood and fluid in the device is returned to the patient and the device is flushed prior to reintroducing the fluid source to the patient.

Accordingly, the improved fluid storage mechanism comprises a cylindrical main body portion having a longitudinal axis generally 25 aligned with the longitudinal axis of a fluid line of a blood sampling system. Disposed within the main body portion is a concentric fluid draw element in sealing relationship therewith and retractable along the longitudinal axis thereof. The fluid draw element includes a fluid conduit extending therethrough with a distal end of the conduit 30 disposed adjacent to a first fluid port provided in the main body portion of the fluid storage mechanism with a second fluid port disposed at a proximal end of the fluid conduit in the fluid draw element.

The fluid storage mechanism also includes a vortex inducer element 35 disposed at the distal end of the fluid conduit provided in the fluid draw element. The fluid draw element is retractable from a first position in which the main body portion receives the fluid draw element in a closed position of minimal fluid capacity to enable fluid flow

-4-

from a fluid supply through the fluid conduit to the patient, to a continuously variable open position to enable withdrawal of fluid and blood into the storage mechanism to insure withdrawal of blood only at the sampling site.

- 5 Additional features of the improved fluid storage mechanism of the present invention includes a contamination sheath overlying the fluid storage mechanism to minimize external contamination of the mechanism during the sampling procedure. In the preferred embodiment of the invention the sheath is disposed between the fluid draw element and the
10 main body portion of the fluid storage mechanism.

The improved fluid storage mechanism as described above is adapted to be disposed along the longitudinal axis of the arterial line extending from the fluid source to the injection site entering the patient. Moreover, such improved fluid storage mechanism includes a main body
15 portion which is generally concentric with the arterial line, with the fluid draw element being concentric as well, thereby minimizing the ability of the device to tip or skew the line and further, enabling the single operator to more efficiently draw fluid and blood into the improved fluid storage mechanism and then to take a sample at the
20 sampling site.

In another embodiment of the present invention, the fluid storage mechanism incorporates a pre-set volume feature which enables the sampling attendant to adjust the mechanism to a pre-set volume by a spiral groove or track on the fluid draw element cooperatively engaging
25 a track guide provided on the interior of the main body portion. The track guide also serves as a locking mechanism which engages an outer edge of the sealing ring associated with the fluid draw element to limit the travel of the fluid draw element and the capacity of the fluid storage mechanism to a fixed maximum volume. Presetting the
30 volume would allow the patient's blood pressure to fill the storage mechanism and minimize damage to the endothelium lining of the vein or artery receiving the catheter.

These and other advantages of the improved fluid storage mechanism will be better understood when the device is considered in light of the
35 detailed description that follows, particularly when such description is considered in conjunction with the drawings provided.

-5-

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a sectional view of the improved fluid storage mechanism of the present invention in the fully closed position;

5 Figure 1B is a view similar to Figure 1A in which the fluid storage mechanism of the present invention has been fully extended to fill a storage chamber therein;

Figure 2 is an enlarged side elevational view of a vortex inducer element of the improved fluid storage mechanism of the present invention;

10 Figure 3 is a view taken along the lines 3-3 of Figure 2;

Figure 4A is a representative sampling system incorporating the improved fluid storage mechanism of the present invention, with the fluid storage mechanism in a fully closed position;

15 Figure 4B shows the sampling system with the fluid storage mechanism in a fluid draw or fully extended position;

Figure 4C shows a blood sampling procedure in progress with the fluid storage mechanism fully extended;

Figure 4D shows the fluid storage mechanism at a mid-point of its return to the fully closed position;

20 Figure 4E shows the fluid storage mechanism in the fully closed position with a flush sequence in progress;

Figure 4F shows the return of the fluid storage mechanism of the sampling system to the fully closed, low-volume flow position of Figure 4A;

25 Figure 5 is a broken line section of the distal end of the fluid storage mechanism wherein is incorporated a first alternative embodiment of the vortex inducer element of Figure 2;

Figure 6 is a view taken along lines 6-6 of Figure 5;

30 Figure 7 is a broken line section of the distal end of the storage mechanism wherein is incorporated a second alternative embodiment of

-6-

the vortex inducer element of Figure 2;

Figure 8 is a side elevational view of the vortex inducer element of Figure 7;

Figure 9 is a bottom view of the vortex inducer element shown in Figure 8;

Figure 10 is an exploded perspective view of an alternative embodiment of the fluid storage mechanism of Figure 1, the alternative embodiment incorporating a volume control feature;

Figure 11a is a side elevational in section of the alternative embodiment of Figure 10, with the fluid draw element and the volume control element fully closed;

Figure 11b is a sectional side elevation similar to Figure 11a in which the volume control element is fully extended and the fluid draw element is fully closed; and

15 Figure 11c is a sectional side elevation of the fluid storage mechanism of the alternative embodiment in which the volume control element and the fluid draw element are both fully extended.

Figures 1A and 1B illustrate the preferred embodiment of the present invention. The present invention comprises an improved fluid storage mechanism 20 including a cylindrical main body portion 21, which tapers to a fluid receiving opening 21a at a distal end thereof and receives a cylindrical fluid draw element 22 concentrically mounted therein. Fluid conduit 23 extends through the fluid draw element 22 to terminate at a distal end 24 thereof and to continue at a proximal end 25 thereof 25 through the fluid storage mechanism 20 to be connected to an external element 26 (Figure 4A) associated therewith as better described below. Disposed at the distal end 24 of the fluid draw element 12 is a vortex inducer element 28 mounted thereon to overlie the distal end of fluid conduit 23.

30 In the fully closed position of the fluid draw element 12 the vortex inducer element 28 on the fluid draw element 22 is disposed adjacent the fluid receiving opening 21a at a tapered distal end 30 of the main body portion 21. The vortex inducer element 28 is described in greater detail below.

5 Adjacent the distal end of the fluid draw element 22 next to the vortex inducer element 28 is a sealing ring 31 which encircles the fluid draw element 22 and engages interior peripheral side wall 32 of the main body portion 21 to define a variable capacity fluid draw chamber 34 between the interior wall 32 of main body portion 21 and the sealing ring 31 of fluid draw element 22 of the fluid storage mechanism 20. Fluid draw chamber 34 is better seen in Figure 1B.

10 15 A flexible anti-contamination sheath 35 is mounted on an exterior wall 33 of the fluid draw element 22 and the interior wall 32 of the main body portion 21 and is attached at the distal end to the fluid draw element at peripheral connection ring 36 and to the proximal end of the interior wall of the main body portion at peripheral connection ring 38.

20 The sheath 35 is comprised of a flexible material, such as a polyethylene which encircles the fluid draw element 22. In the preferred embodiment the sheath 35 shown in Figures 1A and 1B is pleated much like an accordion to expand in the fully open or extended position of the fluid flow mechanism 20 and to close in the fully closed position of the fluid flow mechanism 20. However, any thin flexible material could be employed and pleating of the sheath 35 is not necessary.

25 30 As seen in Figure 1A, the fluid draw element 22 is locked in the fully closed position of the fluid flow mechanism 20 by the cooperation of retainers 40, which are rigidly mounted on opposite sides of the exterior of the main body portion 21 of the fluid flow mechanism 20, with clips 42. The retainers 40 include openings 41 extending therethrough. The openings 41 receive clips 42 which extend outwardly from the base 44 of a U-shaped bracket 45 which is mounted on the proximal end 25 of the fluid draw element 22. The clips 42 are biased outwardly and each terminate in a latching element 46 which is received in a respective opening 41 of a retainer 40 to secure the fluid draw element 22 in the fully closed position shown in Figure 1A.

35 The vortex inducer element 28 is shown in greater detail in Figures 2 and 3 wherein grooves 28, 28b and 28c radiate from a central portion 28d of the element 28 to extend to a respective radial periphery 29 to provide a flow path from fluid conduit 23 into the fluid storage chamber 34. The outer surface of vortex inducer element 28 is tipped to conform generally to the interior of the tapered distal end 30 of the fluid chamber 34 of the fluid flow mechanism 20.

A sampling system incorporating the fluid storage mechanism of the preferred embodiment of the present invention as shown in Figures 1-3 as shown in Figures 4A through 4F. In Figure 4A, a fluid supply 50 is connected by an arterial line 51 to a variable flow control device and 5 flush valve 52. Through an appropriate fitting 26 the flush valve 52 is connected to the proximal end 25 of the fluid storage mechanism 20. The fluid line 51 connected to the distal end of the fluid storage mechanism 20 is in turn connected to a shut-off valve 53 and then to a sampling port 54. Fluid line 51 also connects the sampling port 54 to 10 an injection site 55 through which a catheter 55a is extended into the patient. In the closed position of Figure 4A, fluid flow from the fluid supply 50, through the arterial line 51, through the flush valve 52, through the fluid storage mechanism 20 is at least at a keep-vein-open (K.V.O.) rate to maintain a positive flow of fluid from the fluid 15 supply to the patient.

In Figure 4B the fluid storage mechanism 20 is activated by releasing grips 42 from the brackets 40 to enable a fluid draw from the injection site in which fluid is drawn into the fluid storage chamber 34 of the fluid storage mechanism 20 with valve 53 open. When the storage chamber 20 34 of the mechanism 20 is filled, valve 53 is closed.

As shown in Figure 4C, with valve 53 closed, a sampling container 56 is placed at the sampling port 54 to withdraw a blood sample from the patient through arterial line 51.

As shown in Figure 4D, once the sampling procedure is completed, the 25 valve 53 is opened and the fluid draw element 22 is returned toward the fully closed position of the fluid storage mechanism 20, to transfer the fluid in the fluid draw chamber 34 back into the patient.

During the steps of the blood sampling procedure shown in Figures 4A-4D, flow continues to flow through the fluid conduit 23 of the blood 30 draw element 22 at a low volume or "drip" flow rate. However, the vacuum effect produced by the extending of the fluid draw element 22, as in Figure 4B, enables the arterial flow of blood and fluid from the patient to overcome the drip rate flow from fluid supply 50 and enter the fluid chamber 34 of the fluid flow mechanism 20.

35 In Figure 4E, with the fluid draw element 22 fully closed, variable rate valve 52 is activated at a high volume or flush rate to rapidly discharge any residual blood/fluid mixture from the distal end 30 of fluid chamber 34 of the fluid storage mechanism 20. The fluid flow

-9-

through the fluid path of the vortex inducer element 28 creates a swirl effect at the distal end 30 of storage chamber 34 at the flush rate of the valve 52 to further assist removal of residual fluid from the fluid storage mechanism 20.

- 5 As shown in Figure 4F, thereafter a low volume or drip infusion rate is resumed by the valve 52, to continue infusion of fluids into the patient.

The embodiment of the vortex inducer element 28 shown in Figures 2 and 3 is not the only embodiment available to the user. For example, as shown in Figures 5 and 6, the main body portion 21 of the fluid flow mechanism 20 could incorporate at its distal end 30 a fluid draw element 22 having a fluid conduit 23 therethrough and including a vortex inducer element 60, having a central opening 61 extending from the fluid conduit 23, and having provided on opposite sides of that central opening 61 oppositely facing channels 62 and 63, so as to induce a swirl effect of vortex type flow in the distal end 30 of the fluid chamber 34 of the fluid flow mechanism 20. Circumferential sealing member 31 closes one end of the chamber 34.

In Figures 7-9 a second alternative embodiment of the vortex inducer element of the present invention is shown within a fluid flow mechanism 120 having a main body portion 121, and the fluid storage chamber 134 is defined between a sealing member 131 and interior wall 132 of the main body portion. Disposed within the main body portion 121 is a fluid draw element 122 having a fluid conduit 123 therein with the sealing ring 131 disposed between the outer wall 133 of the fluid draw element 122 and the inner wall 132 of the main body portion 121 with a vortex inducer element 128 mounted at the distal end of the fluid draw element 122 to define multiple fluid paths 141a and 141b at the distal end of the fluid draw element 122.

- 30 Vortex inducer element 128 is better seen in Figures 8 and 9. An upper face 142 conforms generally to the distal end 130 of the fluid storage mechanism 120. At the bottom or base 138 of the vortex inducer element 128 are a plurality of ribs 139a, 139b, 139c and 139d. The ribs 139a,b,c,d radiate from a central bottom portion 140 to a peripheral edge 142 to define between the ribs 139 and the base 138 of the vortex inducer element 128 fluid flow channels 141a, 141b, 141c and 141d. Although a preferred embodiment and two alternative embodiments of the vortex inducer element have been shown, it is to be understood that other embodiments are possible and that the alternative embodiments may

-10-

not be restricted to grooves alone or ridges alone, but may be a combination of the two.

As shown in Figures 10 and 11, the fluid storage mechanism of the present invention may also incorporate a volume control feature. For 5 example, a fluid flow mechanism 220 includes a main body portion 221, a fluid draw element 222 having a fluid conduit 223 therein, a vortex inducer element 228 at the distal end of the fluid draw element 222 and a circumferential sealing ring 231 disposed at the distal end of the fluid draw element 222, with a fluid storage chamber 234 defined 10 between the main body portion 221 and the sealing ring 231 of fluid draw element 222.

In the alternative embodiment of Figures 10 and 11, disposed behind the sealing ring 231 of the fluid draw element 222 is a volume control device 240 having an outer cylindrical deanti-contamination shell 241 15 and a cylindrical volume control shell 242 disposed within the circumferential interior wall 232 of the main body portion 231. Provided on the exterior wall 243 of the cylindrical shell 242 are a pair of spiral grooves 244 and 245 displaced 180° apart as best seen in Figure 10. Received in the grooves 244 and 245 are respective groove 20 or track guides 246 and 247.

Provided on the exterior of the main body portion 221 and associated with the fluid chamber 234 is a set of markings 248 to indicate the volume gradations as the volume control device 240 is moved along 25 grooves 244, 245 from the fully closed position of the fluid storage mechanism 220 to the fully extended position of the fluid storage mechanism 220. The fluid draw element 222 has a longitudinal body portion 222a slideably received in a rear opening 251 in the volume control device 240.

The operation of the fluid storage mechanism 220 is better seen in 30 Figures 11a through 11c. In Figure 11a, the fluid storage mechanism 220 is shown in the fully closed position, with the fluid draw element fully closed and the volume control device 240 engaged against a bottom wall 250 of the fluid draw element 222.

In Figure 11b, the volume control device 240 is withdrawn away from end 35 wall 250 of the fluid draw element 222 to the extreme end of tracks 244 and 245 with the fluid draw element 222 remaining at the fully closed position.

-11-

- With the volume control device 240 withdrawn away from the bottom of the fluid draw element 222, there is no force to retain the fluid draw element in place and the arterial flow from the patient forces the fluid draw element backward until the bottom wall 250 of the fluid draw element engages the end of the fluid control device 240 as seen in Figure 11c. Although the volume control device 240 was set at an extreme end position for illustrative purposes in Figures 11a through 11c, such volume control device could be set at any intermediate position to preset a specific volume for the fluid chamber 234.
- 10 The above description sets forth the preferred embodiment of the present invention and those alternatives known to the inventor. It is to be understood that various modifications and additions may be made to the preferred embodiment without departing from the spirit and scope of the present invention. Such modifications as may be obvious to one skilled in the art may be implemented to adapt the present invention for use in conjunction with a variety of different applications. However, the scope of the present invention is to be defined by the claims set forth below.
- 15

-12-

CLAIMS

1. A fluid storage mechanism usable in a blood sampling system including a fluid line extending from a fluid supply to a patient, said system comprising an injection site entering the patient at a distal end of the fluid line, a fluid container disposed at the proximal end 5 of the fluid line, a sampling site disposed proximally of the injection site, means enabling fluid flow from the fluid supply at variable rates, and a fluid storage mechanism interposed between the sampling site and the fluid supply to facilitate sampling, the fluid storage mechanism comprising:
 - 10 a main body portion having a longitudinal axis thereof generally aligned with the longitudinal axis of the fluid line;
 - a concentric fluid draw element disposed within said main body portion in sealing relationship therewith and retractable along the longitudinal axis thereof;
 - 15 a fluid path provided through the fluid storage mechanism including a first fluid port provided in the main body portion;
 - a fluid conduit provided in the fluid draw element extending from a distal end disposed adjacent said first fluid port to a proximal end thereof; and
 - 20 a vortex inducer element mounted at the distal end of the fluid conduit provided in the fluid draw element and having a fluid path therethrough, with the fluid draw element retractable from a first sealed position, in which the main body portion receives the fluid draw element in a closed position of minimal fluid capacity to enable fluid 25 flow from the fluid supply through the fluid conduit to the patient, to a continuously variable open position to enable withdrawal of blood and fluid into the fluid storage mechanism to assure withdrawal of blood only at the sampling site, and returnable to the closed position to return the fluids therein to the patient, with activation of the fluid 30 flow means at a flush rate for cleansing blood and fluid from the fluid storage mechanism.
2. A fluid storage mechanism as claimed in Claim 1 wherein the fluid flow enabling means is disposed adjacent the fluid supply between the fluid storage mechanism and the fluid supply.
3. A fluid storage mechanism as claimed in Claim 1 wherein the fluid draw element includes a sealing member disposed adjacent the distal end thereof and a longitudinal segment retaining the fluid conduit therein and extending generally along a longitudinal axis of 5 the main body portion of the fluid storage mechanism.

-13-

4. A fluid storage mechanism as claimed in Claim 1 wherein the vortex inducer element comprises a disk-like member having an upper surface and lower surface, the upper surface generally terminating at a point to conform its shape to the shape of the distal end of the main body portion of the fluid storage mechanism, and a lower surface including at least one groove radially extending from the center of the disk to an outer periphery of the disk, the groove spiralled from its central inner end to its radial outer end to induce a spiral flow of fluid from the distal end of the fluid conduit in the fluid draw element and into the fluid storage chamber of the fluid storage mechanism.

5. A fluid storage mechanism as claimed in Claim 4 wherein the vortex inducer element comprises a top face and a bottom face and disposed on the bottom face are a plurality of spiral grooves emanating from a central portion of the bottom face and extending outwardly to a peripheral edge thereof.

6. A fluid storage mechanism as claimed in Claim 4 wherein the peripheral grooves comprise three spiral grooves equally spaced at the peripheral edge of the bottom face of the vortex inducer element.

5. A fluid storage mechanism as claimed in Claim 1 wherein the vortex inducer element includes upper and lower faces and disposed on the lower face thereof is a central portion having fluid channels disposed at opposite ends thereof with a first fluid channel extending to one peripheral edge of the element and a lower fluid channel extending to an opposite peripheral edge of the lower face, to dispose exit ports of the fluid channels approximately 180° apart.

8. A fluid storage mechanism as claimed in Claim 1 wherein the vortex inducer element comprises upper and lower faces, with the upper face generally conforming to the distal end of the main body portion of the fluid storage mechanism and the lower face including a plurality of ridges therein, each of said ridges extending from an open central portion of the bottom face and extending to a peripheral edge thereof with a plurality of fluid channels, each defined between each successive pair of ridges provided on the vortex inducer element.

-14-

9. A fluid storage mechanism as claimed in Claim 1 wherein a anti-contamination sheath is attached to an exterior distal end of the fluid draw element and a proximal end of the main body portion of the fluid storage mechanism to prevent contamination of the fluid sample
5 drawn into the fluid storage mechanism from an external source.

10. A fluid storage mechanism as claimed in Claim 1 wherein the fluid storage mechanism includes a main body portion having volume gradations marked thereon, a volume control device having at least one spiral groove provided therein and extending from a distal end to a
5 proximal end of the volume control device, and a track guide protruding inwardly of the main body portion and engaging the spiral groove in the volume control device, the volume control device receiving the fluid draw element in cooperative relation, whereby the engagement of the track guide in the groove of the volume control device at a fixed
10 position enables controlled extension of the fluid draw element from the main body portion of the fluid storage mechanism, thereby to enable entry of a pre-set volume of fluid from the patient into the fluid storage mechanism.

1 / 8

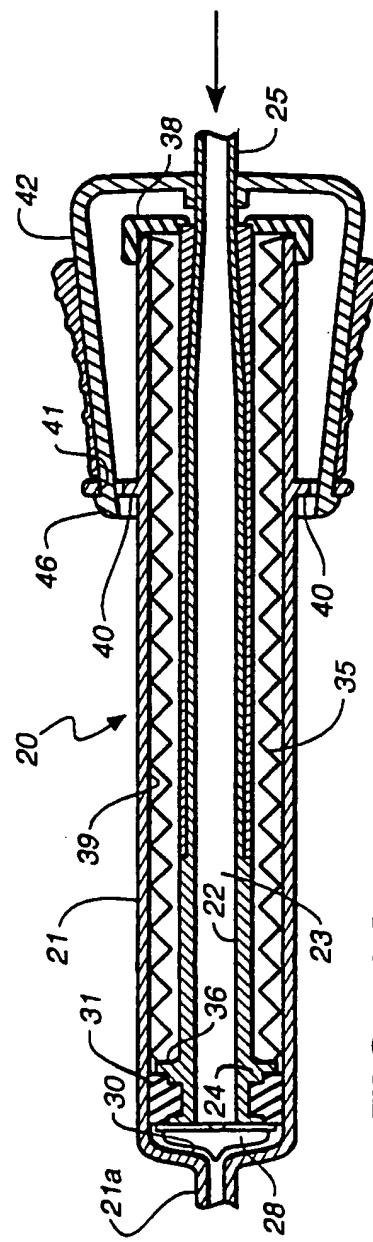


FIG. - 1A

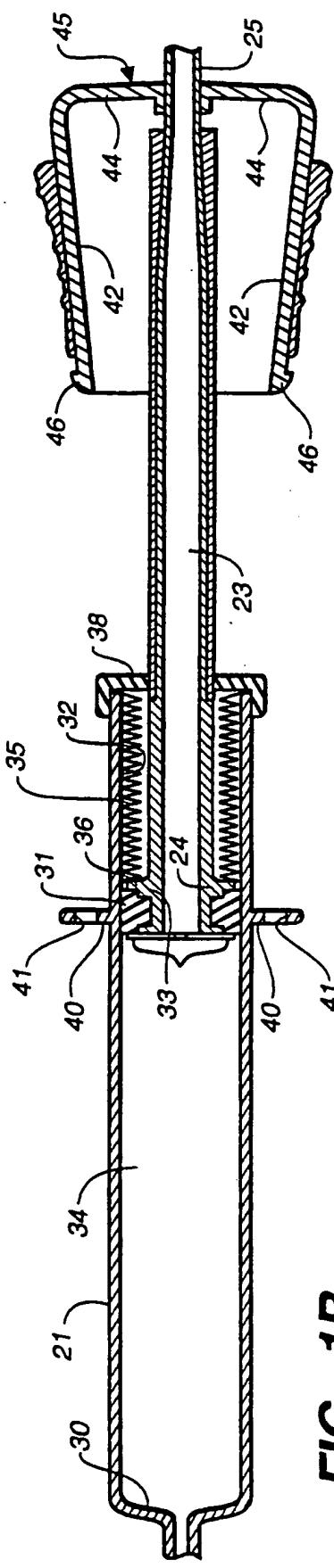


FIG. - 1B

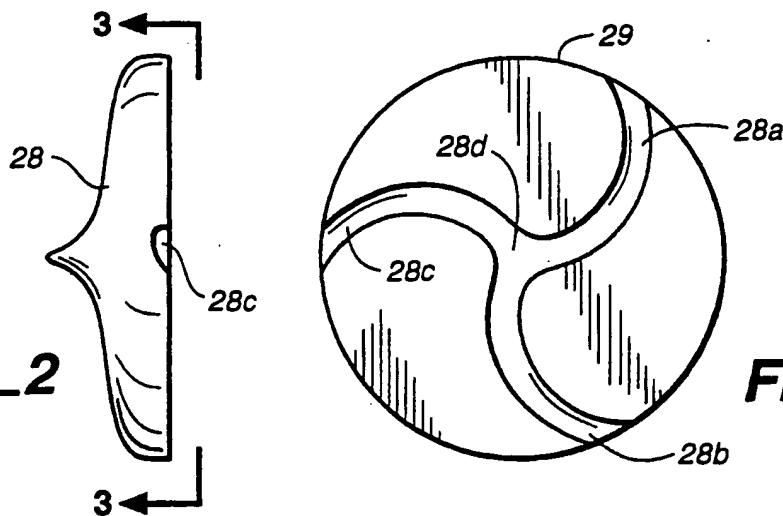


FIG._2

FIG._3

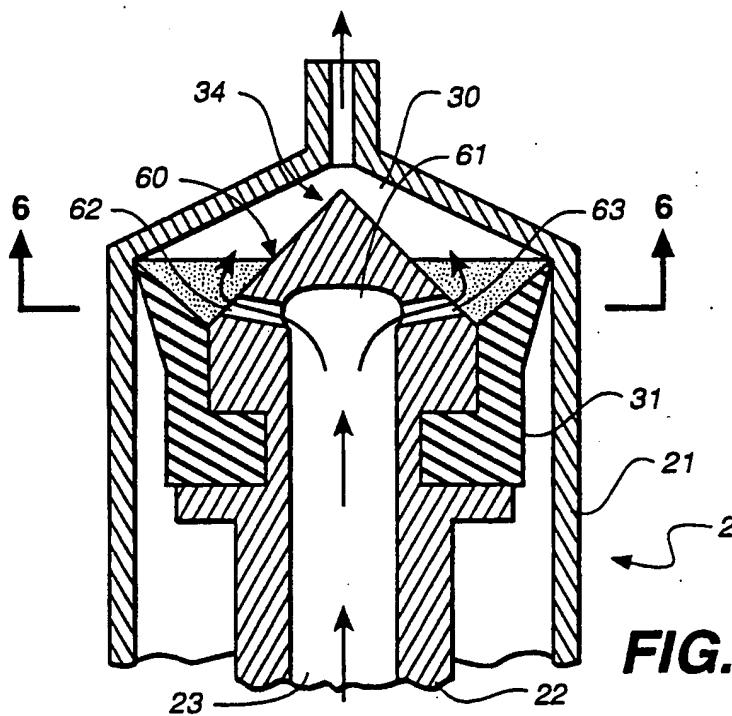


FIG._5

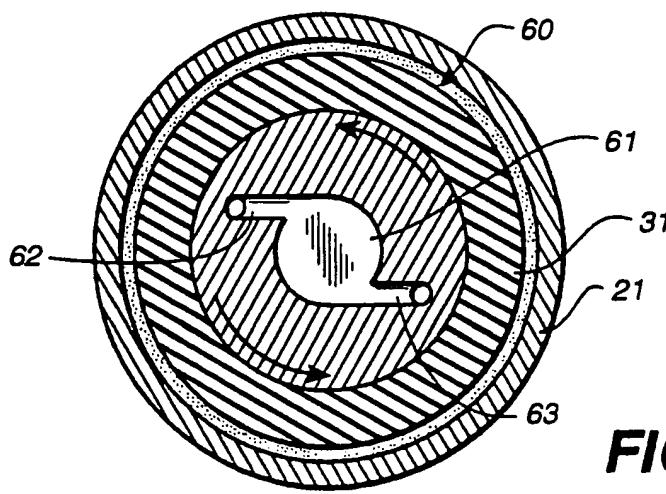
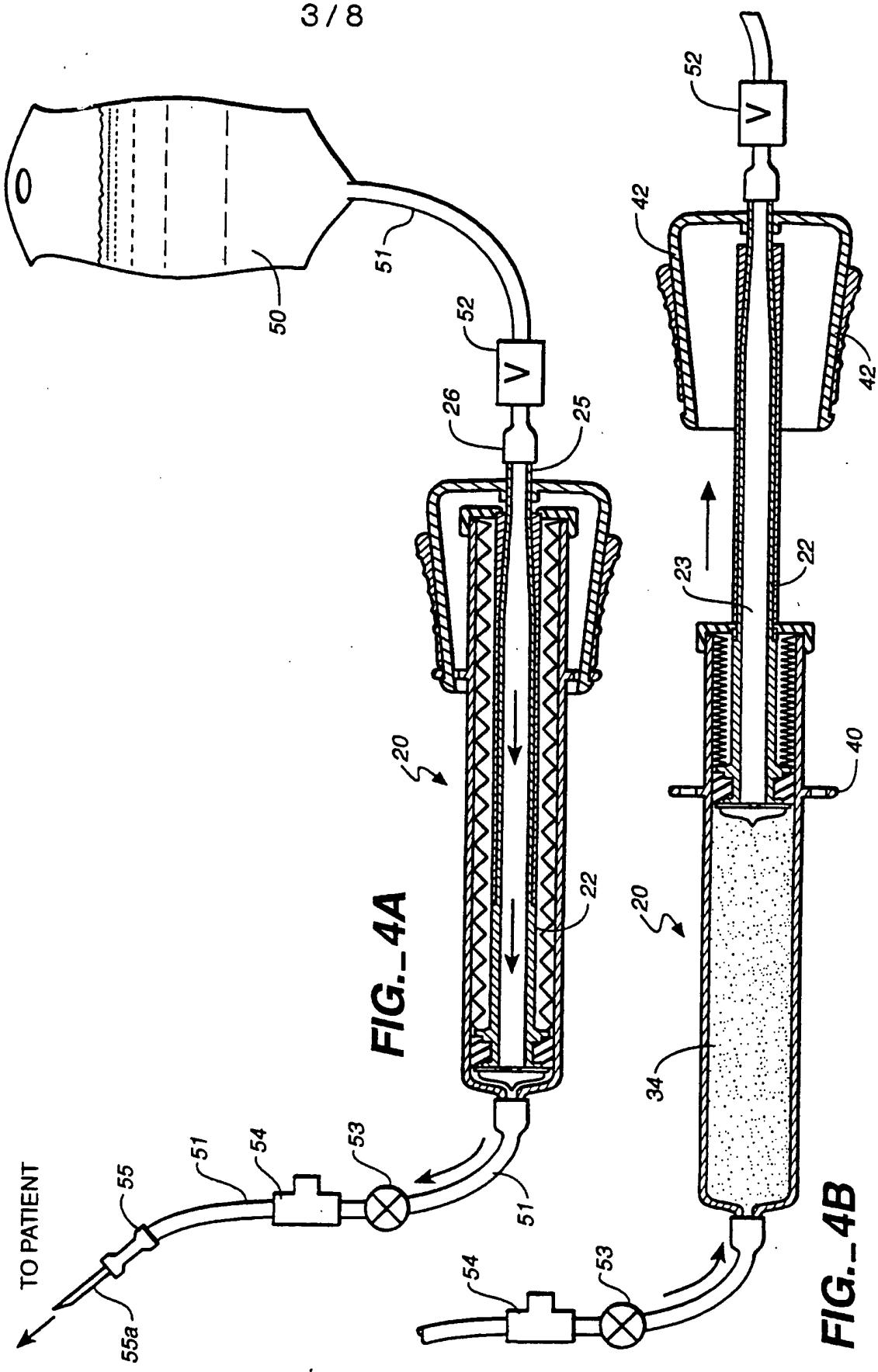


FIG._6

3 / 8



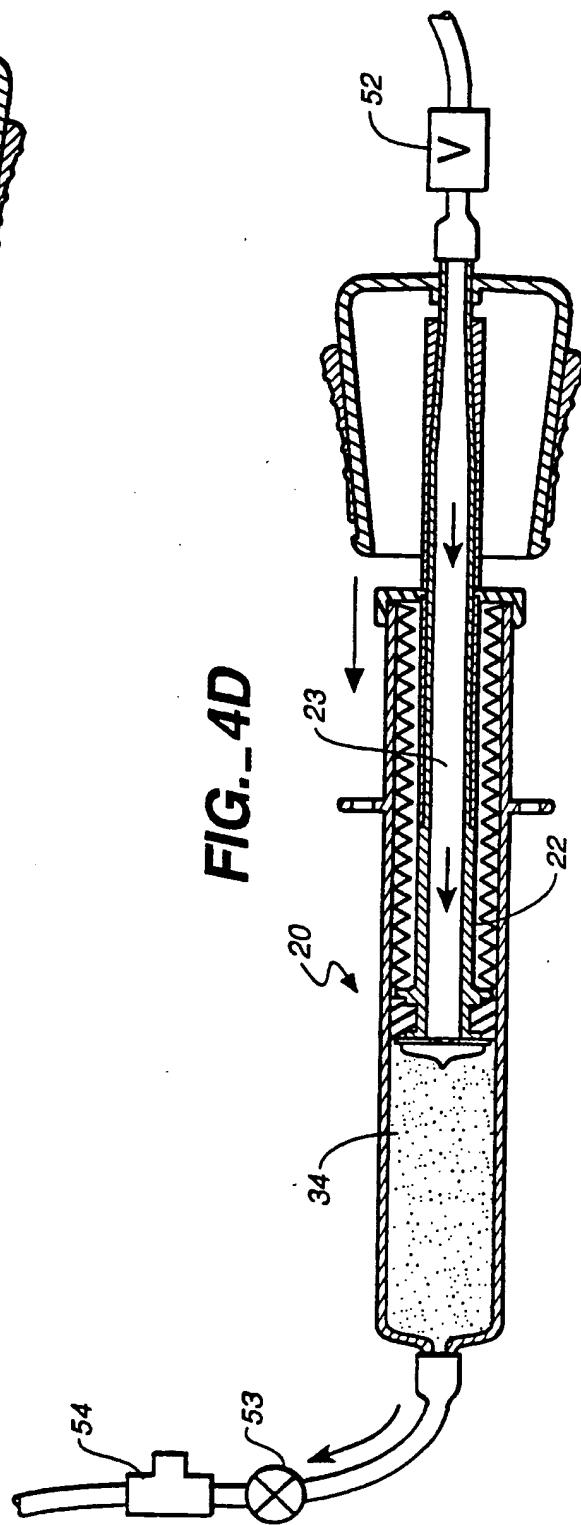
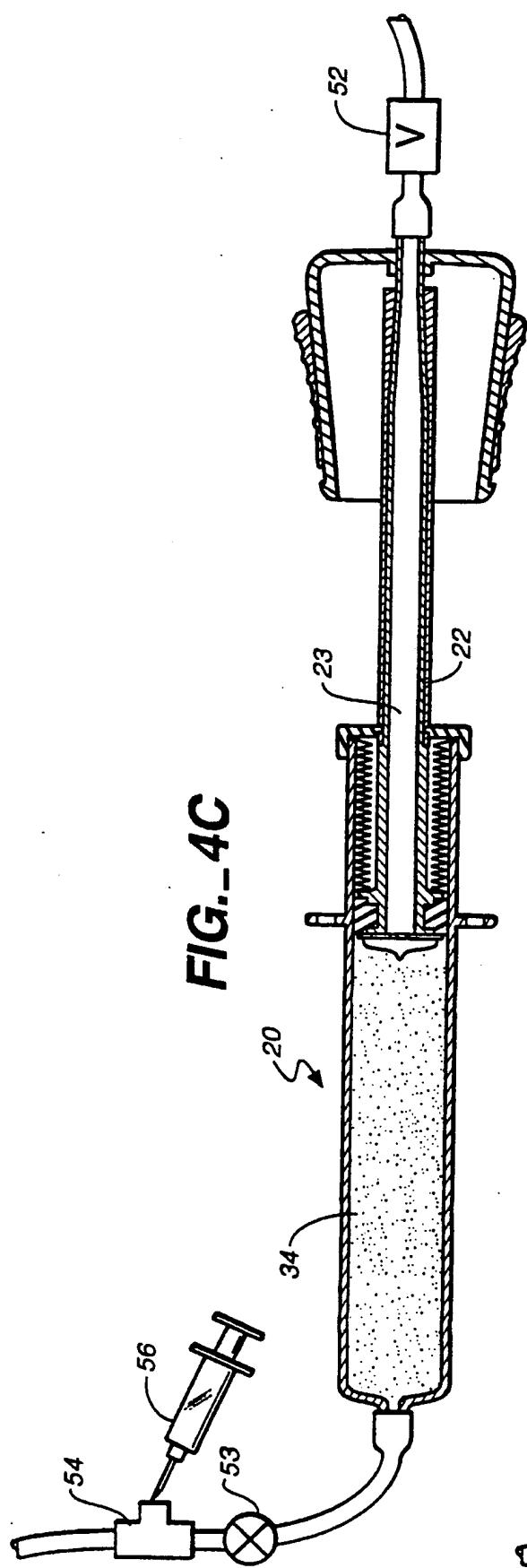


FIG. 4E

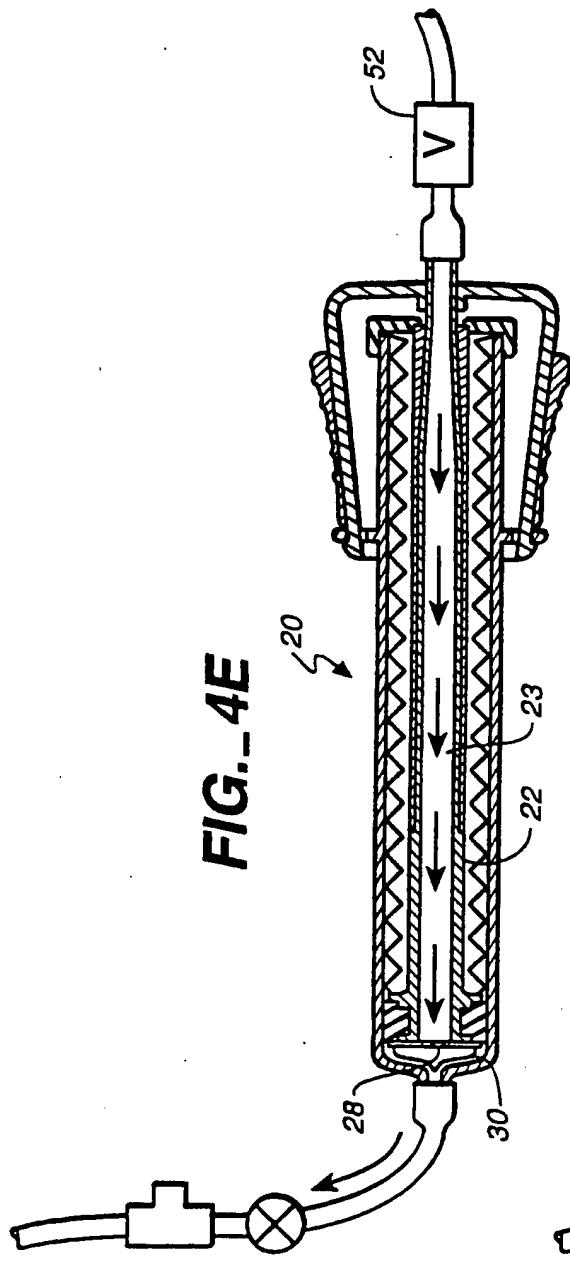
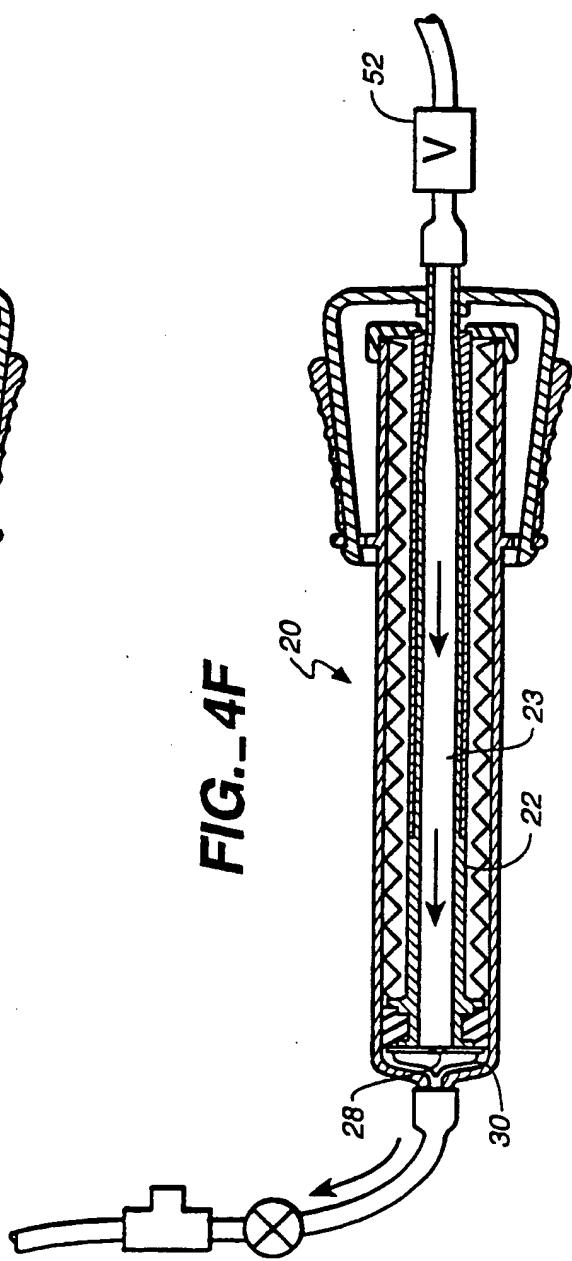
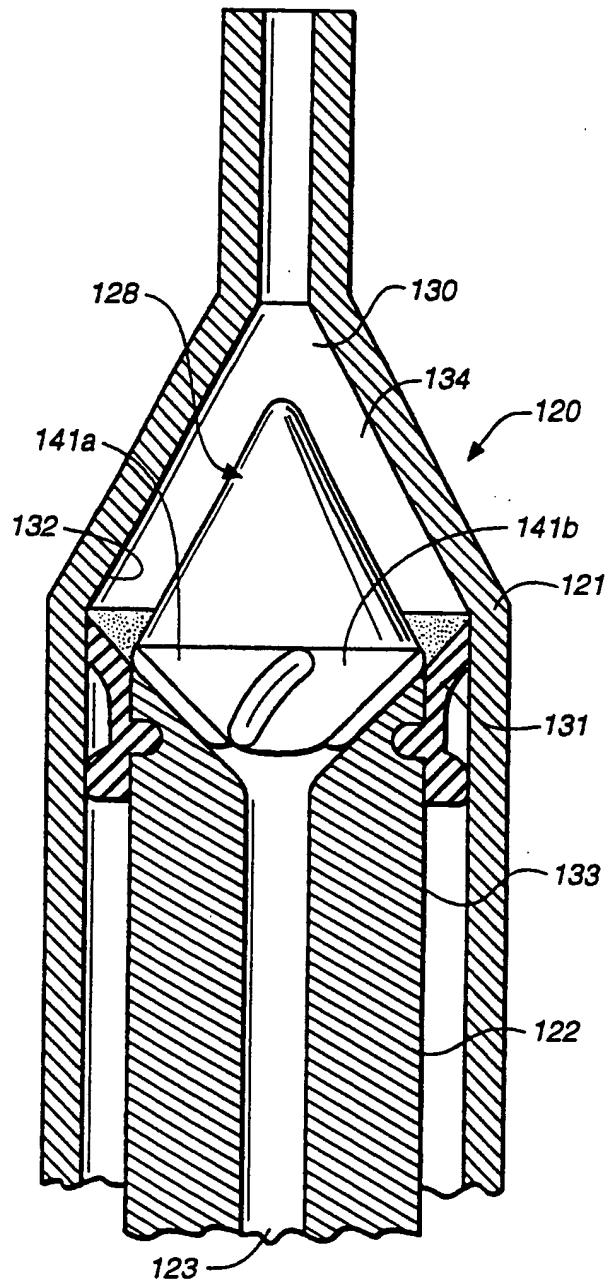
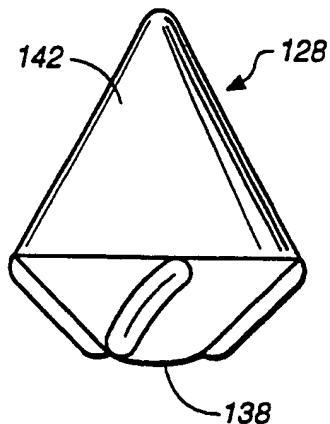
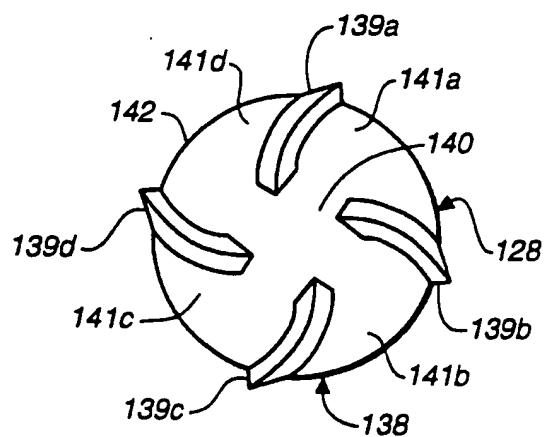


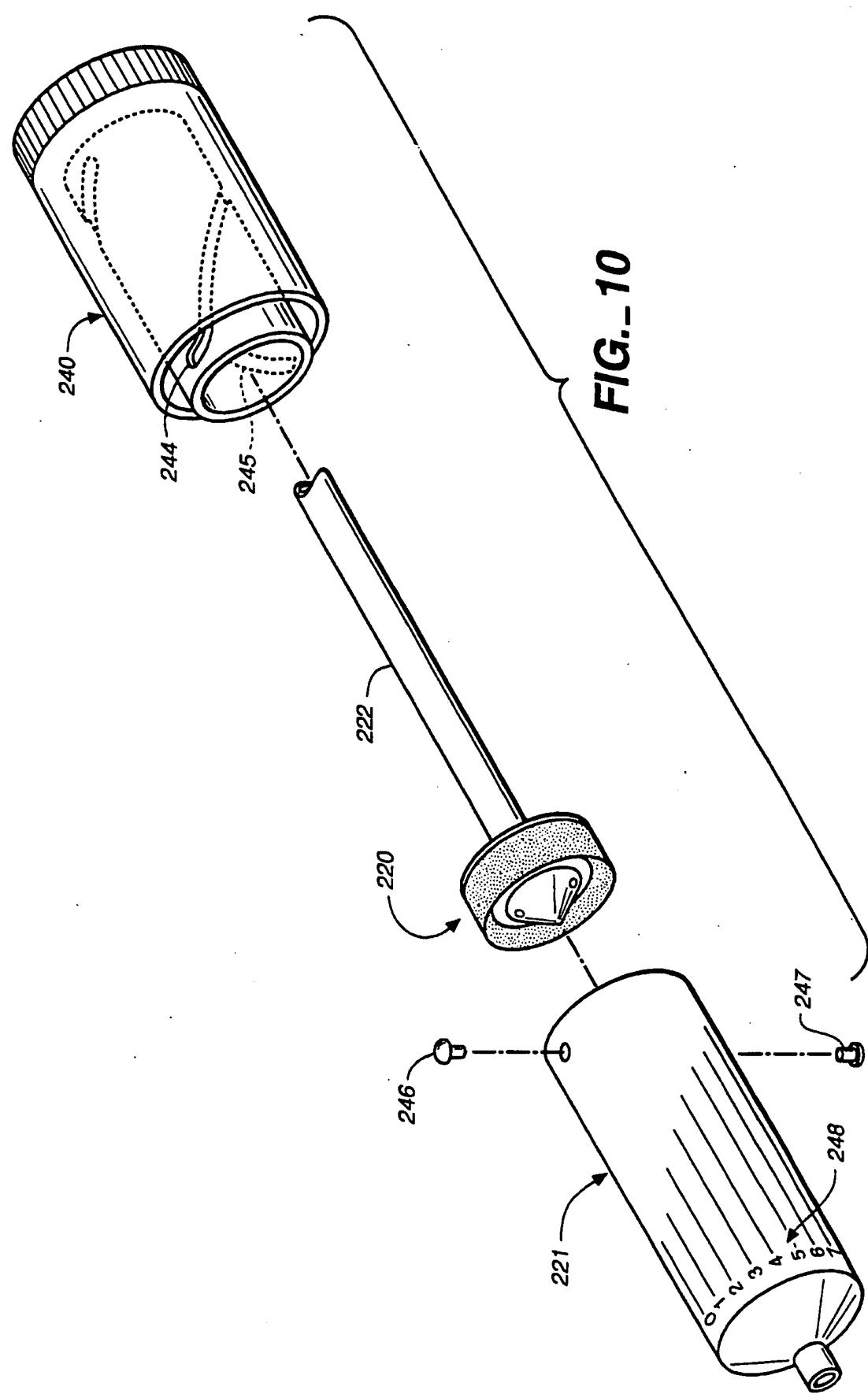
FIG. 4F

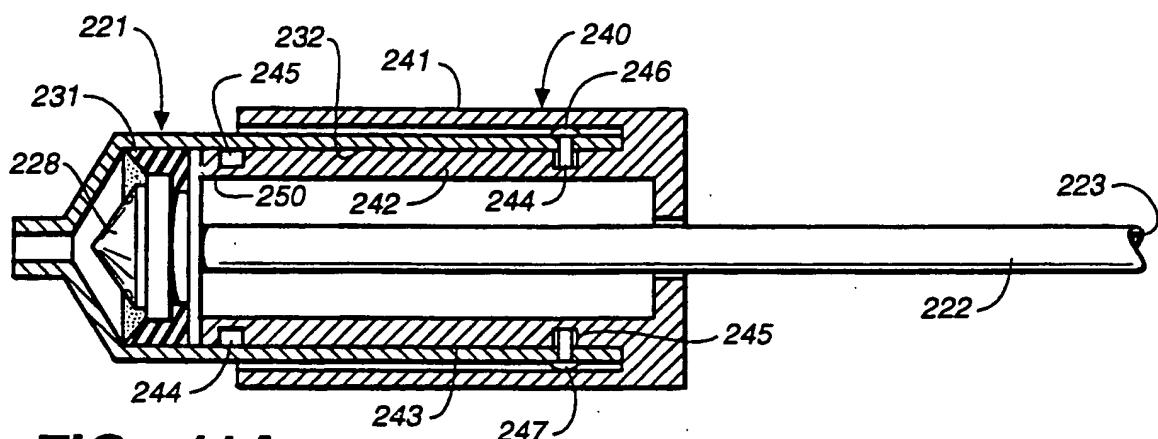
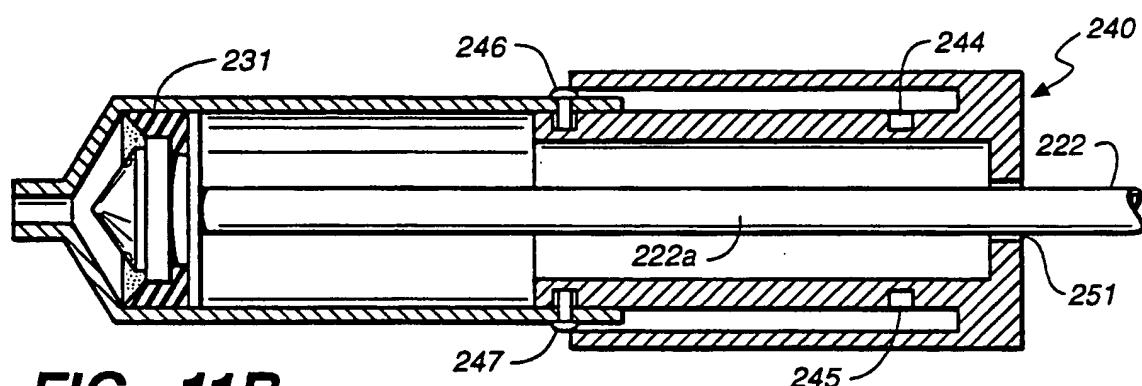
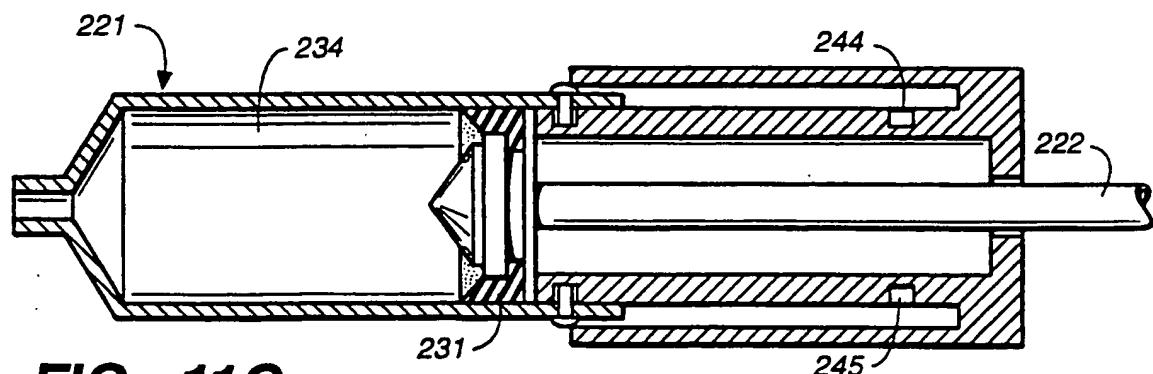


6 / 8

**FIG._7****FIG._8****FIG._9**

7 / 8



**FIG._11A****FIG._11B****FIG._11C**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/10205

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61M 1/00, 5/178, 5/00, 5/315
US CL : 604/125, 184, 211, 231, 900

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/125, 184, 211, 231, 900

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
US: 604/38, 124, 187, 208, 218; 128/765

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	NL, C, 76711 (Claasen) 15 December 1954, see Figs. 1 and 2.	1-3
--		-----
Y		10
Y	US, A, 4,744,955 (Shapiro) 17 May 1988, see Figs. 9-12 and column 3 line 65 to column 4 line 13.	10
A	US, A, 4, 934,379) (Marzolf et al.) 19 June 1990	None
A	US, A, 5, 147, 329 (Brannon) 15 September 1992.	None
A	US, A, 4,257,426 (Bailey) 24 March 1981.	None
A	US, A, 2,861, 571 (E.R. Sandhage et al.) 25 November 1958.	None



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*'A'	document defining the general state of the art which is not considered to be part of particular relevance	"X"
*'E'	earlier document published on or after the international filing date	"X"
*'L'	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"
*'O'	document referring to an oral disclosure, use, exhibition or other means	"Y"
*'P'	document published prior to the international filing date but later than the priority date claimed	*&
		document member of the same patent family

Date of the actual completion of the international search

15 DECEMBER 1993

Date of mailing of the international search report

MAR 01 1994

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. NOT APPLICABLE

Authorized officer

TODD E. MANAHAN

Telephone No. (703) 308-0858

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/10205

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	UA, , 4,457,755 (Wilson) 03 July 1984.	None
A	FR, A, 1.046.541 (Beaumont) 07 December 1953.	None
A	US, A, 5,032,117 (Motta) 16 July 1991.	None
A	FR, A, 1,046,541 (Beaumont) 07 December 1953.	None
A	IT, A, 705,322 (Torino) 02 May 1966.	None